| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/009,491 | VILLA ET AL. | |
| | Examiner | Art Unit | |
| | Susan Tran | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Receipt is acknowledged of applicant's Priority Document, Information Disclosure Statement, and Amendment filed 12/13/01.

### *Claim Objections*

Claim 4 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits. It is suggested to amend the claim to depend in claim 1.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiyama et al. US 5,593,690.

Akiyama teaches sustained release composition comprising active ingredient being dispersed within a fatty acid of a polyglycerol matrix (lipophilic matrix), and an outer coating layer, including cellulose derivatives, sugar, starch, polymer or copolymer of methacrylic acid (see abstract, and column 5, lines 55 through column 6, lines 1-67). The active ingredient can be selected from drugs, such as anti-biotic agents, AD-5467,

or salicylic acid (column 5, lines 1-25). The process of preparing the composition is disclosed in columns 5-7.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franco et al. GB 2 245 492 A.

Franco teaches pharmaceutical dosage form comprising active a core; a coating layer comprises hydrophobic material having melting point from 50-90°C, surfactant, and water-soluble film forming material; and an enteric coating layer (see abstract and page 13). The hydrophobic coating material can be wax, hydrogenated castor oil, fatty acid esters, and mono-, di-, or tri-glycerides (page 7, lines 24 through column 8, lines 1-15). The water-soluble film forming material can be polymer or copolymer of acrylic or methacrylic acid, cellulose or cellulose derivatives (page 8, lines 24-30). The active agent used in the core can be selected from a variety of drugs, including mesalamine (page 10). The enteric coating or gastro-resistant coating material can be selected from methacrylic acid, methacrylic acid ester copolymer, cellulose phthalate, or polyvinyl acetate phthalate (page 12, lines 13-26). The process of preparing the dosage form is

disclosed in pages 10-12, and the examples). The composition can be in tablet, granule or capsule form (id).

It is noted that Franco teaches the use of surfactant in addition to the hydrophobic and the film-forming materials. While applicant's generic claim recites the transitional phrase "consisting of" to exclude other components in the lipophilic matrix, applicant's specification includes (discloses) the use of surfactant, *e.g.*, sodium starch glycolate, and magnesium stearate (examples). Furthermore, applicant's generic claim recites "an inner lipophilic matrix consisting of *substances*". It is the position of the examiner that the phrase "substances" allows the present of substance, including surfactant. Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation optimize Franco's dosage form with the expectation of at least similar result, because Franco teaches the advantageous results in the use of controlled release oral dosage form useful for releasing of drug in the colon.

Claims 1-5, 8, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al.

Akiyama is relied upon for the reason stated above. In the case that the applicant can overcome the above 102(b) rejection, it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to modify Akiyama's sustained release dosage form to obtain the claimed invention, because Akiyama teaches the advantageous result in the use of lipophilic matrix to control the release of active agent to a specific site.

Claims 1-9, and 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanghvi et al. US 5,851,555, in view of Straub et al. US 6,395,300.

Sanghvi teaches controlled release formulation comprising water-soluble drug dispersed in a lipophilic coating, a cellulosic polymer, and compressed into tablet (columns 2-4).

Sanghvi does not teach the specific water-soluble drug.

Straub teaches porous matrix microparticle in oral dosage form comprising water-soluble drug including mesalamine (abstract, and column 7, lines 21-44). Thus, it would have been obvious for one of ordinary skill in the art to modify Sanghvi's controlled release formulation using the water-soluble drug of Straub with the expectation of at least similar result, because the references teach the advantageous results in the use of lipophilic matrix to control the release of water-soluble drugs.

***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Igari et al., Busetti et al., and Bauer are cited as being of interest for the teachings of matrix sustained release preparation containing 5-aminosalicylic agent.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-

5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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